

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : Subhashis Banerjee et al.

Serial No. : 10/622,928

Filed : July 18, 2003

Entitled : TREATMENT OF METABOLIC  
DISORDERS USING TNFALPHA  
INHIBITORS

ART UNIT: 1641

EXAMINER: David J. Blanchard

Attorney Docket No. BBC-203

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING**

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*October 19, 2005*

date of mailing and signature

*Daphne Miller*

Daphne Miller

**TRANSMITTAL LETTER**

Sir/Madam:

Transmitted herewith are: [X] Change of Attorney Docket Number and Change of Correspondence Address; [X] An Information Disclosure Statement under 37 CFR §§ 1.56, 1.97 and 1.98; [X] Form PTO-1449 Information Disclosure Statement; [X] A photocopy of each reference cited; and [X] An Acknowledgement Postcard; to be filed in the above-identified patent application.

**FEE FOR ADDITIONAL CLAIMS**

[X] A fee for additional claims is not required.

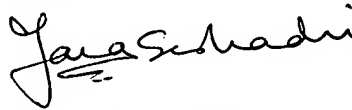
[ ] A fee for additional claims is required. The additional fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE	FEES DUE
TOTAL CLAIMS		41	0	× \$18	= 0.00
INDEPENDENT		12	0	× \$84	= 0.00
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM				+\$280	= 0.00
TOTAL FEES DUE					= 00.00

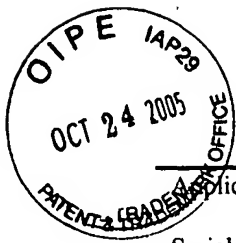
PETITION FOR EXTENSION OF TIME

- [ ] Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the paper(s) filed herewith: [ ] \$110.00 for response within first month pursuant to 37 CFR 1.17(a)(1);  
[ ] \$430.00 for response within second month pursuant to 37 CFR 1.17(a)(2);  
[ ] \$980.00 for response within third month pursuant to 37 CFR 1.17(a)(3);  
[ ] \$1,530.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4).  
[ ] \$2,080.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).
- [X] The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to **Deposit Account No. 010025**. A duplicate copy of this transmittal letter is transmitted herewith.

Respectfully submitted,



Tara Seshadri, Ph.D.  
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Registration No. 48,591  
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*October 19, 2005*  
Date

*Daphne Miller*  
Daphne Miller

**Change of Attorney Docket Number and Change of Correspondence Address (37 CFR 1.8(a))**

Sir/Madam:

Please note that the Attorney Docket No. for the above-identified application has been changed  
from BPI-191 to BBC-203.

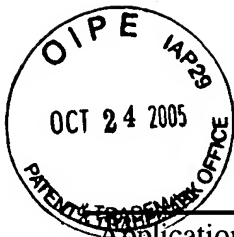
Please send all correspondence relating to the above patent application to:

Tara Seshadri  
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Respectfully submitted,

*Tara Seshadri*

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Daphne Miller

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.56, 1.97 AND 1.98

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

U.S. Patent Documents

Salfeld et al., July 18, 2000, U.S. Patent No. 6,090,382

Salfeld et al., July 10, 2001, U.S. Patent No. 6,258,562

Salfeld et al., January 21, 2003, U.S. Patent No. 6,509,015

#### Foreign Patent Documents

Kempeni et al., December 19, 2002, WO 02/100330

Fischkoff et al., January 15, 2004, WO 2004/004633

Krause et al., February 26, 2004, WO 2004/016286

Kaymakalan et al., May 6, 2004, WO 2004/037205

Salfeld et al., August 14, 1997, WO 97/29131

#### Other Publications

Baeder *et al.*, (1992) *Clin Exp Immunol.* 89:174-178

Bailey *et al.*, (1982) *Int. J. Obesity* 6:11-21

Barbieri M. *et al.*, (2003) *Am J Hypertens.* Jul;16(7):537-543

Benjafield *et al.*, (2001) *Diabetes Care.* Apr;24(4):753-757

Bluher M, *et al.*, (2001) *Diabetes Care.* Feb;24(2):328-334.

Bray & York (1971) *Physiological reviews.* 51:598-646

Chu *et al.* (2000) *Int J Obes.* 24:1085-1092

Clausell N, *et al.*, (1999) *Cardiovasc Pathol.* May-Jun;8(3):145-151.

Coleman, (1978) *Diabetologia*, 14:141-148

Daimon M *et al.*, (2003) *Diabetes Care.* Jul;26(7):2015-2020

Devaraj S, *et al.*, (2000) *Circulation.* Jul 11;102(2):191-196.

Grundy, S. M. & Barnett, J. P., (1990) *Dis. Mon.* 36: 645-731

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Makino *et al.* (1980): *Exp. Anim.* 29:1-13

McCall JL, *et al.*, (1992) *Br J Surg.* Dec;79(12):1361-1363.

Mishima Y, *et al.*, (2001) *Diabetes Res Clin Pract.* May;52(2):119-123.

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Old, L. (1985) *Science* 230:630-632  
Pfeiffer *et al.* (1997) *Horm Metab Res*. 29:111-114  
Pihlajamaki J, *et al.*, (2003) *Obes Res*. Jul;11(7):912-917.  
Qiang, X. *et al.* (1998) *Diabetologia*.41:1321-1326  
Scholz *et al.* (2003) *Trends Microbiol*. 11:171-178  
Spiegelman BM, *et al.*, (1993) *Cell*. May 21;73(4):625-627.  
Tsuda T, *et al.*, (2003) *J Nutr*. Jul; 33(7):2125-2130.  
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Venn *et al.* (1993) *Arthritis Rheum*. 36:819-826  
Westacott CI, *et al.*, (1994) *J Rheumatol*. Sep; 1(9):1710-1715.  
Westman (1968) *Diabetologia* 4:141-149  
Zhang *et al.* (1999) *J Tongji Med Univ*. 19:203-205  
Zinman B, *et al.*, (1999) *J Clin Endocrinol Metab*. Jan; 4(1):272-278.

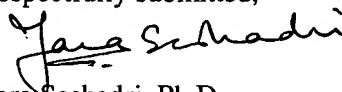
Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

This paper is being mailed before the mailing of a first Office action. Pursuant to 37 CFR §1.97(b)(4), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,



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Approved for use through 07/31/2006. OMB 0651-0031

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Sheet	1	of	6
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Application Number	10/622,928
Filing Date	July 18, 2003
First Named Inventor	S. Banerjee
Art Unit	1641
Examiner Name	David J. Blanchard
Attorney Docket Number	BBC-203

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		WO 02/100330	12-19-2002	Abbott Biotechnology Ltd.		
		WO 04/004633	01-15-2004	Abbott Biotechnology Ltd.		
		WO 04/016286	02-26-2004	Abbott Laboratories (Berm		
		WO 04/037205	05-06-2004	Abbott Biotechnology Ltd.		
		WO 97/29131	08-14-1997	BASF Aktiengesellschaft		

Date  
Considered

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 6

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BAEDER et al, "Rapamycin prevents the onset of insulin-dependent diabetes mellitus (IDDM) in NOD mice", Clin Exp Immunol (1992)89, 174-178	
		BAILEY et al, "Influence of genetic background and age on the expression of the obese hyperglycaemic syndrome in Aston ob/ob mice", Int. J. Obesity (1982)6, 11-21	
		BARBIERI et al, "Is Chronic Inflammation a Determinant of Blood Pressure in the Elderly?", Am J. Hypertens (2003 Jul)16(7), 537-543	
		BENJAFIELD et al, "TNFRSF1B in Genetic Predisposition to Clinical Neuropathy and Effect on HDL Cholesterol and Glycosylated Hemoglobin in Type 2 Diabetes", Diabetes Care (2001 Apr) 24(4), 753-757	
		BLUHER et al, "Plasma Levels of Tumor Necrosis Factor-alpha, Angiotensin II, Growth Hormone, and IGF-I Are not Elevated in Insulin-Resistant Obese Individuals with Impaired Glucose Tolerance", Diabetes Care (2001 Feb)24(2), 328-334	
		BRAY & YORK, "Genetically Transmitted Obesity in Rodents", Physiological Reviews, (1971) 51, 598-646	
		CHU et al, "Glycemic status and soluble tumor necrosis factor receptor levels in relation to plasma leptin concentrations among normal weight and overweight US men" Int J Obes (2000) 24, 1085-1092	
		CLAUSELL et al, "Increased Expression of Tumor Necrosis Factor-alpha in Diabetic Macrovasculopathy", Cardiovasc Pathol, (1999 May/June)8(3), 145-151	
		COLEMAN, "Obese and Diabetes: Two Mutant Genes Causing Diabetes-Obesity Syndromes in Mice", Diabetologia (1978)14, 141-148	
		DAIMON M, et al, "Decreased Serum Levels of Andiponectin Are a Risk Factor for the Progression to Type 2 Diabetes in the Japanese Population", Diabetes Care (2003 Jul) 26(7), 2015-2020	

Examiner Signature	Date Considered
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		DEVARAJ et al, "Low -Density Lipoprotein Postsecretory Modification, Monocyte Function, and Circulating Adhesion Molecules in Type 2 Diabetic Patients With and Without Macrovascular Complications", Circulation (2000 Jul 11), 102(2), 191-196	
		GRUNDY & BARNETT, "Metabolic and Health Complications of Obesity" Dis. Mon. (1990) 36, 645-731	
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		HOTAMISLIGIL et al, "Increased Adipose Tissue Expression of Tumor Necrosis Factor-alpha in Human Obesity and Insulin Resistance", J. Clinl Invest (1995)95, 2409-2415	
		HOTAMISLIGIL GS et al, "Adipose Expression of Tumor Necrosis Factor-alpha: Direct Role in Obesity-Linked Insulin Resistance", Science (1993 Jan 1)259, 87-91	
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		KATSUKI et al, "Serum Levels of Tumor Necrosis Factor-alpha Are Increased in Obese Patients with Noninsulin-Dependent Diabetes Mellitus", J Clin Endocrinol Metab (1998 Mar)83(3), 859-862	
		KOLB, "Mouse Models of Insulin Dependent Diabetes: Low-Dose Streptozocin-Induced Diabetes and Nonobese Diabetic (NOD) Mice", Diabetes/Metab Rev (1987)3, 751-778	

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4

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		LECHLEITNER et al, "Tumour necrosis factor-alpha plasma levels in elderly patients with Type 2 diabetes mellitus-observations over 2 years" Diabetes Med (2002) 19 (11), 949-953	
		LEE et al, "TNF and TNF Receptor Polymorphisms in Korean Behcet's Disease Patients", Human Immunol (2003)64(6), 614-620	
		MAKINO et al, "Breeding of a Non-Obese, Diabetic Strain of Mice", Exp Anim (1980)29, 1-13	
		MCCALL et al, "Serum tumour necrosis factor alpha and insulin resistance in gastrointestinal cancer" Br. J. Surg (1992 Dec)79(12), 1361-1363	
		MISHIMA et al, "Relationship between serum tumor necrosis factor-alpha and insulin resistance in Obese men with Type 2 diabetes mellitus" Diabetes Res Clin Pract (2001) 52(2), 119-123	
		MULLER et al, "Impaired glucose tolerance is associated with increased serum concentrations of interleukin 6 and co-regulated acute-phase proteins but not TNF-alpha or its receptors", Diabetologia (2002) 45, 805-812	
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		NISHINA et al, "Atherosclerosis in Genetically Obese Mice: The Mutants Obese, Diabetes, Fat, Tubby, and Lethal Yellow" Metab (1994)43, 554-558	
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			Filing Date	July 18, 2003	
			First Named Inventor	S. Banerjee	
			Art Unit	1641	
			Examiner Name	David J. Blanchard	
Sheet	5	of	6	Attorney Docket Number	BBC-203

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		PIHLAJAMAKI et al, "The Effect of the-308A Allele of the TNF-alpha Gene on Insulin Action Is Dependent on Obesity", Obes Res (2003 Jul)11(7), 912-917	
		QIANG et al, "Inhibitory effect of troglitazone on diabetic neuropathy in streptozotocin-induced diabetic rats", Diabetologia (1998)41, 1321-1326	
		SCHOLZ et al, "Human cytomegalovirus retinitis: pathogenicity, immune evasion and persistence", Trends Microbiol (2003)11, 171-178	
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		Application Number	10/622,928		
		Filing Date	July 18, 2003		
		First Named Inventor	S. Banerjee		
		Art Unit	1641		
		Examiner Name	David J. Blanchard		
Sheet	6	of	6	Attorney Docket Number	BBC-203

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ZINMAN et al, "Circulating Tumor Necrosis Factor- $\alpha$ Concentrations in a Native Canadian Population with High Rates of Type 2 Diabetes Mellitus", J Clin Endocrinol Metab (1999 Jan) 4(1),272-278	

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